

REMARKS

The Official Action of March 25, 2003, has been carefully reviewed. The claims in the application are now claims 1-37 and 44-46, the non-statutory "use" claims 38-43 having been deleted without prejudice. Applicant's claims define patentable subject matter and should be allowed. Applicant accordingly respectfully requests favorable reconsideration and allowance.

Acknowledgement by the PTO of the receipt of applicant's papers filed under Section 119 is noted.

The PTO has acknowledged receipt of a preliminary amendment A stated to have been filed January 8, 2002, and another preliminary amendment B and IDS filed on February 20, 2002. According to applicant's records, the first preliminary amendment, i.e. the preliminary amendment correcting claim 24, was filed September 25, 2001.

The PTO has noted that it has not checked applicant's specification to the extent necessary to determine the presence of all possible minor errors, and has requested applicant's cooperation relative thereto. Applicant is certainly amenable to full cooperation, and awaits any further

commentary from the PTO as to the presence of any minor errors which the Examiner might notice.

With respect to Appendix A, applicant attaches herewith a clean copy of such Appendix which corresponds to pages 34-36 of the present application.

The PTO states that the present application currently names joint inventors. This is incorrect. Only one inventor is named.

Restriction has been required by the PTO on the basis that the various groups of inventions listed in the Office Action "are not so linked as to form a single general inventive concept under PCT Rule 13.1", i.e. that there is an absence of unity of invention.

As applicant must make an election even though the requirement is traversed, applicant hereby respectfully repeats the oral election made over the telephone on or about March 5 or 6, 2003¹, i.e. applicant respectfully and provisionally elects phenyl 1,3-cyclicglycerophosphate (claim 9) with traverse and without prejudice, and points out that phenyl 1,2-cyclicglycerophosphate (Claim 6) is structurally quite similar.

¹ There was an even earlier oral election of claims 1-24 on December 30 or 31, 2002.

First, applicant does not really understand the restriction requirement as it appears in the Official Action. It appears to be inconsistent with PCT Rules 13.1 and 13.2. It appears to require applicant to claim only a single compound. Inconsistently, it refers on page 6 of the Office Action to the examiner having built a subgeneric group "disclosed in Group I", yet Group I seems to be directed to **only a single compound.** Furthermore, Groups I-V are all identified identically, and directed to identically the same compound.

Applicant is thus left facing a restriction requirement which makes sense to applicant, and to which applicant cannot reasonably reply except to make an election (as has been previously and above) under great protest, and to strongly traverse the requirement.

The restriction requirement states that the inventions listed in Groups I through VI do not relate to a single general inventive concept under PCT Rule 13.1 because they lack the same or corresponding special technical feature as required by PCT Rule 13.2, the reasoning being that "the compounds and compositions defined in the claims lack a significant structural element qualifying as the special technical feature that defines a contribution over the prior art." With great respect, the PTO cannot make such a

statement unless it shows such prior art. As of now, the corresponding technical feature under PCT Rule 13.1 which provides a single general inventive concept under PCT Rule 13.1 is the compounds of formula I as defined in the claims.

In other words, applicant has presented generic claims which, to the best of applicant's knowledge, are patentable over any known prior art. The broadest of these claims thus define the "corresponding special technical feature" which extends through **all** of applicant's claims. There is no basis for any holding by the PTO of lack of unity of invention.

Applicant notes that applicant's position in this regard is fully consistent with what occurred during the international phase of the present application, and in this regard attention is respectfully invited to the International Preliminary Examination Report (IPER), especially form PCT/IPEA/409 (cover sheet), part 3, box IV, entitled "lack of unity of invention" **which is not checked**. During the international phase, the application was found to have unity of invention. Applicant respectfully points out that the PTO, being part of the U.S. Government, is bound by treaty obligations of the United States of America.

The restriction requirement in this case is absolutely unfounded and improper and should be withdrawn. It

certainly makes no sense that applicant is entitled to claim only a single compound. It is clear that many of applicant's compounds are structurally similar to one another. Applicant accordingly respectfully requests withdrawal of the restriction requirement and examination of all the claims on the merits.

New claims 44-46 have been added above which are generic to the elected species. These represent the 1,3-cyclicglycerophosphates of the present invention. All such compounds are well supported in the present application as filed. The chemical and biological examples given in the specification all well support these cyclic propandiol and glycerophosphate compounds.

The synthesis of such compounds is provided in example 1 (1,3 cyclic glycerophosphate), example 3 (phenyl 1,3 cyclic glycerophosphate), example 4 (1,3 cyclic propandiolphosphate) and example 6 (phenyl 1,3cyclic propandiolphosphate). The biological activity of these compounds is given in examples 12-16 (related to tyrosine phosphorylation), and examples 30-32 (cancer treatment) and as shown in the figures.

These new claims are patentable for the same reasons as all of the other claims. Applicant notes that no *prima facie* case of unpatentability has been established by the PTO.

Indeed, no prior art at all has been applied against any of applicant's claims. Applicant accordingly understands that all of applicant's claims are deemed by the PTO to define novel and unobvious subject matter under §§102 and 103.

Further in this regard, applicant notes that the prior art documents of record have not been relied upon, and applicant accordingly notes the implication that such documents of record are deemed by the PTO to be insufficiently pertinent to warrant their application against any of applicant's claims.

Further in this regard, applicant notes the commentary in the first full paragraph on page 7 of the Official Action that "the compounds and methods of use commensurate in scope [with the elected subject matter] would be allowable."

Only one rejection has been made, and that only of claims 13 and 14. Thus, claims 13 and 14 have been rejected under the first paragraph of §112 as being nonenabling for the treatment of malignant diseases. The rejection is respectfully traversed.

First, attention is respectfully invited to page 8, lines 24-28 of applicant's specification which states as follows:

One cellular process which involves phosphorylation in intracellular proteins is cell differentiation. The present invention also provides a pharmaceutical composition a pharmaceutically acceptable carrier and, as an active material, a compound of the general Formula I above for promotion of cell differentiation in target cells.

The next paragraph beginning at line 29 describes in its first sentence that the ability of the compounds of the present invention "to induce cell differentiation... makes them especially suitable for use in the treatment of... various malignancies." The same paragraph mentions, besides breast cancer and blood malignancies such as leukemias and lymphomas, "other solid tumors such as brain tumors, etc."

Moreover, applicant has never alleged and has not claimed that applicant's compounds are effective against all malignant diseases. This constitutes a misreading of claim 13. Nevertheless, to make explicit what was implicit, a clause has been added at the end of claim 13 to specify that the malignant disease or disorder is one against which the compound in question provides an effective treatment. Please see *In re Sarrett*, 140 USPQ 474,486 (CCPA 1964). Please especially see *In re Geerdes*, 180 USPQ 789,791, 793 (CCPA 1974), wherein the Court stated in part as follows:

Finally, we cannot agree... that the claims are inclusive of materials which would not apparently be operative in the claimed process. The claims call for producing a [specific result]. Having stated the

objective... together with the process steps, use of materials which might prevent achievement of the objective [by rendering the process inoperative] can hardly be said to be within the scope of the claims.

The rejection under §112 was reversed.

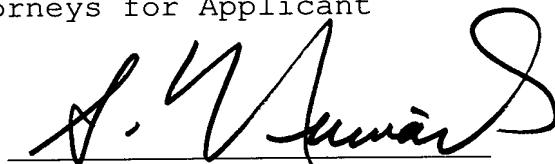
Applicant respectfully requests withdrawal of the rejection.

Favorable reconsideration and allowance are earnestly solicited.

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C.
Attorneys for Applicant

By



Sheridan Neimark
Sheridan Neimark
Registration No. 20,520

SN:jaa
Telephone No.: (202) 628-5197
Facsimile No.: (202) 737-3528
G:\BN\C\cohn\Shinitzky4\PTO\amd 20JE03.doc

Appendix A

	Formula	Abbreviation
I		1, 3 cGP
II		1, 2cGP
III		cyclic lysophosphatidic acid, c-lysoPA
IV		P-1, 3cGP
V		P-1, 2cGP
VI		1, 3cPP

Appendix A

	Formula	Abbreviation
VII		1,2cPP
VIII		P-1,3cPP
IX		P-1,2,cPP
X		CDHAP
XI		P-CDHAP